

REMARKS

The following remarks are responsive to the Office Action mailed November 12, 2009 (hereinafter, “Office Action”). As discussed below, Claims 1-15 and 31-35 remain pending in the present application, and new Claims 35-37 are added by this Amendment.

Claim Rejections:

While Applicants respectfully disagree with the Examiner’s rejections, to advance prosecution, Applicants have amended one or more claims to address the Examiner’s comments. Applicants are not acquiescing to the rejections and reserve the right to pursue in a related application claims at least as broad as the amended claims prior to the amendments set forth herein. Applicants respectfully request the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

Claim Rejections – 35 U.S.C. 103:

Applicants submit that the Office Action again fails to present a *prima facie* obviousness rejection because the Office Action fails to satisfy the required burden in establishing an obviousness rejection based, in part, on the requirements set forth in the Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*

For example, as will be described in greater detail below, the proposed combinations involve several modifications and changes to the prior art. However, the Office Action fails to articulate specific rationales for the proposed combinations and modifications of the references, while also ignoring the whole teachings of the prior art references.

Rejection of Claims 1-15 under 35 U.S.C. 103(a):

Claims 1-15 and 31-34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent No. 5,769,885 (“Quiachon”) in view of Patent Application No. 5,607,445 (“Summers”) and United States Patent No. 5,647,857 (“Anderson”). Although Applicants disagree with this rejection, Claims 1 and 10 have been amended herein to advance prosecution.

For the reasons set forth below, Applicants submit that Quiachon's intraluminal grafting system, modified as taught by Summers and Anderson, does not disclose, suggest, or render obvious the bifurcation graft deployment systems of amended Claims 1 and 10.

In particular, with regard to Claim 1, Applicants submit that Quiachon in view of Summers and Anderson does not disclose, suggest, or render obvious a bifurcated prosthesis deployment system comprising,

an elongate, flexible catheter body, having a proximal end and a distal end and comprising an outer sheath and an inner core that is axially moveable with respect to the outer sheath and an atraumatic distal tip coupled to the inner core and positioned adjacent the distal end of the catheter body;

a self-expanding bifurcated graft comprising a main vessel portion, a first branch vessel portion, and a second branch vessel portion;

a main vessel graft restraint comprising a first peelable cover for restraining substantially the entire length of the main vessel portion of the bifurcated graft;

a first branch vessel graft restraint, for restraining the first branch vessel portion of the graft; and

a second branch vessel graft restraint, for restraining the second branch vessel portion of the graft;

wherein:

the first peelable cover is coupled to a main branch release element;

each of the bifurcated graft, main vessel graft restraint, first branch vessel graft restraint, and the second branch vessel graft restraint are positioned within the catheter body in a graft loaded condition in an orientation such that the main vessel portion is positioned nearer to the distal end of the catheter body than either the first branch vessel portion or the second branch vessel portion; and

the first peelable cover is configured to tear as it is being proximally retracted.

Further, with regard to Claim 10, Applicants submit that Quiachon in view of Summers and Anderson does not disclose, suggest, or render obvious a deployment system for deploying a bifurcated prosthesis at the junction of a main vessel and first and second branch vessels, comprising:

a delivery catheter having an inner core, an outer sheath and a distal tip that is coupled to the inner core, the inner core being slidably engaged within the outer sheath; and

a self-expanding bifurcated prosthesis having a main body section with proximal and distal ends and being self-expandable along a substantial portion of the length thereof, and first and second branch sections at the proximal end of the main body section, each being self-expandable along a substantial portion of the length thereof;

wherein:

at least a portion of the main body section is held in a radially compressed state by a first peelable cover, the first branch section is held in a radially

compressed state within a first tubular cover, and the second branch section is held in a radially compressed state within a second tubular cover;

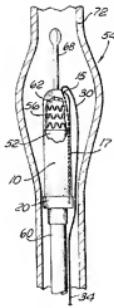
the main body section is deployable by proximally retracting the first peelable cover;

the first peelable cover is configured to tear as it is being proximally retracted; and

the compressed bifurcated prosthesis is positioned within the outer sheath such that the distal end of the bifurcated prosthesis is positioned nearer to the distal tip of the delivery catheter.

In contrast with Claims 1 and 10, Anderson does not disclose, suggest, or render obvious that “the first peelable cover is configured to tear as it is being proximally retracted,” as set forth in Claims 1 and 10. In contrast, as pointed out in the Office Action at page 3, Anderson “teach[es] the use of a peelable sheath (restraint) over an entire length of a graft with a release element [] to allow the sheath to be peeled away from the graft instead of slid or displaced axially to prevent retraction of the sheath from displacing or distorting the graft during deployment.”

Similarly, as stated in the abstract of Anderson, “[t]he sheath is removed from the graft by pulling on the free end of the strand otherwise located distally from the outer surface of the sheath. The strand cuts through and splits open the sheath as a result of the force applied on the free end of the strand. The other end of the strand is attached to a reinforced collar at the other end of the sheath. The strand does not cut through the collar. After reaching the collar, the proximal force applied on the strand now pulls the split sheath from the graft and stent combination without disturbing the placement of the stent over the balloon delivery catheter.



Therefore, in Anderson, the sheath is not retracted until *after* it has been split open by the strand, whereas, in Claims 1 and 10, the first peelable cover is configured to tear *as* it is being proximally retracted. This is shown in the Figures 17 – 19 of Applicants' application, reproduced below for reference.

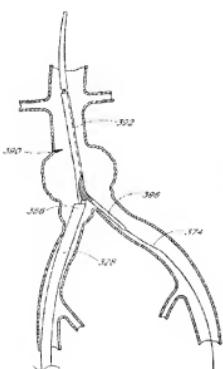


FIG. 17

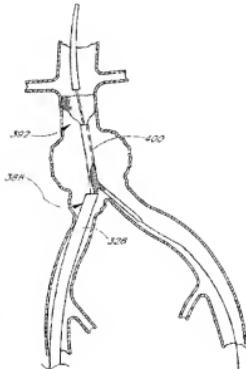


FIG. 18

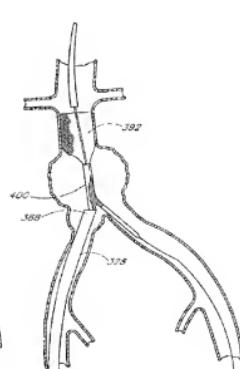


FIG. 19

That the first peelable cover is configured to tear as it is being proximally retracted is an important distinction relative to the disclosure of Anderson because, for Applicants' bifurcated graft, removing the cover simultaneously with the deployment of the graft minimizes the risk that the cover will become snagged or pinched between the graft and the vessel wall against which the graft is expanding during deployment. Therefore, Applicants respectfully submit that Anderson does not disclose, suggest, or render obvious the inventions of Claims 1 and 10.

Regarding dependent Claims 2-9, 11-15, and 31-34, Applicants submit that these claims are not anticipated or suggested by, or unpatentable over, the cited references for at least the reasons stated above with respect to Claims 1 and 10 and also because they each recite further patentable distinctions.

For example, Claim 33 is directed to the deployment system of Claim 1, wherein the main branch release element is connected to a proximal end portion of the first peelable cover and does not extend distally past the proximal end portion of the first peelable cover. Similar to other limitations set forth in Claims 1 and 10, this is also distinct from the disclosure in Anderson and

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enables the cover to be retracted as it is being opened to minimize the risk of the cover being pinched between the graft and the vessel wall.

For the foregoing reasons, Applicants respectfully request the Examiner to also withdraw the rejection of Claims 1-15 and 31-34, and to pass these claims to allowance.

New Claims Have Been Added:

New Claims 35-37 have been added. Applicants submit that these claims are fully supported by the application as filed such that no new matter has been introduced by this Amendment, and that these claims are directed to elected inventions. Regarding the art references cited in the Office Action, Applicants submit that Claims 35-37 are not anticipated or suggested by, or unpatentable over, the cited references for at least the reasons stated above with respect to Claims 1 and 10 and also because they each recite further patentable distinctions.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/417,651 ENDOLOG.007C4	ENDOLUMINAL VASCULAR PROSTHESIS	05-03-2006

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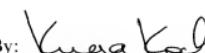
11/623,679 ENDOLOG.007C5	ENDOLUMINAL VASCULAR PROSTHESIS	01-16-2007
10/119,525 ENDOLOG.014C1	SELF EXPANDED BIFURCATED ENDOVASCULAR PROSTHESIS	04-08-2002
11/417,883 ENDOLOG.014C2	SELF EXPANDED BIFURCATED ENDOVASCULAR PROSTHESIS	05-03-2006
10/706,660 ENDOLOG.028C2	DUAL WIRE PLACEMENT CATHETER	11-12-2003
10/820,455 ENDOLOG.054A	ENDOLUMENAL VASCULAR PROSTHESIS WITH NEointima INHIBITING POLYMERIC SLEEVE	04-08-2004
11/104,303 ENDOLOG.056A	METHOD AND APPARATUS FOR DECOMPRESSING ANEURYSMS	04-12-2005
11/580,201 ENDOLOG.056CPI	METHOD AND APPARATUS FOR DECOMPRESSING ANEURYSMS	10-12-2006
11/522,292 ENDOLOG.067A	MULTI-SEGMENTED GRAFT DEPLOYMENT SYSTEM	09-15-2006
11/623,022 ENDOLOG.075A	DUAL CONCENTRIC GUIDEWARE AND METHODS OF BIFURCATED GRAFT DEPLOYMENT	01-12-2007
12/257,149 ENDOLOG.085A	STENT	10-23-2008
11/189,101 ENDOLOG.21CP6C2	BIFURCATION GRAFT DEPLOYMENT CATHETER	07-25-2005
11/417,926 ENDOLOG.21CP7C2	IMPLANTABLE VASCULAR GRAFT	05-03-2006
11/764,715 ENDOLOG.21CP7CC	IMPLANTABLE VASCULAR GRAFT	06-18-2007
10/690,227 ENDOLOG.23DVIC1	SINGLE PUNCTURE BIFURCATION GRAFT DEPLOYMENT SYSTEM	10-21-2003
11/214,427 ENDOLOG.4C3C1	BIFURCATED VASCULAR GRAFT AND METHOD AND APPARATUS FOR DEPLOYING SAME	08-29-2005
12/269,677 ENDOLOG.091A	METHOD AND AGENT FOR IN-SITU STABILIZATION OF VASCULAR TISSUE	11-12-2008
12/101,863 ENDOLOG.093A	BIFURCATED GRAFT DEPLOYMENT SYSTEMS AND METHODS	04-11-2008
12/390,346 ENDOLOG.096A	DESIGN AND METHOD OF PLACEMENT OF A GRAFT OR GRAFT SYSTEM	02-20-2009

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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